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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,681	02/25/2004	Shanta Modak	A34446-A-PCT-USA-AA	3011

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BAKER BOTTS L.L.P.
30 ROCKEFELLER PLAZA
44TH FLOOR
NEW YORK, NY 10112-4498

EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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11/21/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTSCOM

Office Action Summary

Application No.

10/786,681

Applicant(s)

MODAK ET AL.

Examiner

Jagadishwar R. Samala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09/06/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/29/2007 & 10/18/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed on 09/06/2007. Upon entering the amendment claim 1 is amended. The pending claims are 1-2 and presented for examination.

Information Disclosure Statement

2. The Information Disclosure Statement filed on 08/29/2007 AND 10/18/2007 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant office action.

Response of Arguments

3. Applicant's arguments filed on 09/06/2007 with respect to claims under U.S.C. 35 103(a) have been fully considered but they are not persuasive. The 103(a) rejection of Modak et al (US 5,965,610) or Jampani et al. (US 5,980,925) in view of Beilfuss et al (US 5,516,510) is maintained and made Final.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al (US 5,965,610) or Jampani et al. (US 5,980,925) in view of Beilfuss et al (US 5,516,510).

Modak discloses a composition comprising an irritant-inactivating agent such as anti-microbial agent and an anti-binding substance, which substantially prevents the irritant-inactivating agent from binding to the surface (e.g. soluble zinc compounds). And also discloses various anti-microbial agents such as iodine, benzalkonium chloride, phenoxyethanol, triclosan, chlorhexidine digluconate (see column 5, lines 2-25). Further

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discloses pharmaceutically acceptable cationic substance used to block binding sites on the skin such as zinc acetate, zinc gluconate, zinc oxide, zinc stearate, and zinc salicylate (see column 7, lines 10-12) and when the irritant-inactivating agent is an anti-microbial agent, and when the anti-binding substance is zinc, the ratio of the amount of the anti-microbial agent to the amount of the anti-binding substance is preferably from about 1:13 to about 2:1 (see column 9, lines 2-6). Further cationic substance include quaternary ammonium compounds such as amino acids and peptides, quaternized proteins such as cocodimonium hydroxypropyl hydrolyzed keratin (see column 7, lines 14-23).

Jampani discloses a composition comprising anti-microbial agent and a dermal anchoring/skin agent such as glycerin (see abstract). And also discloses various anti-microbial agents, chlorhexidine or its derivatives such as chlorhexidine digluconate, benzalkonium chloride, parachlorometaxylenol, iodine, triclosan, quaternary ammonium compounds (e.g. cationic peptides, organometallic antiseptics, alkyl pyridinium salts) and metal cationic substance is zinc oxide (see column 3, lines 2-12).

Modak and Jampani fails to disclose octoxyglycerin in a composition. However, the incorporation of octoxyglycerine to enhance the activity of active ingredients, such as anti-microbial agents is well known in the art as shown by Beilfuss.

Beilfuss discloses a composition comprising anti-microbial agent and glycerine monoalkyl ethers such as octoxyglycerin. The preferred anti-microbial agents include phenoxy ethanol, chlorhexidine salts, as well as salts of other cation-active compounds with deodorizing action. The glycerin monoalkyl ethers incorporated are mild and skin-

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compatible, have a good spreading capacity and confer a pleasant skin feeling, they are particularly suitable for deo-compositions. The glycerin monoalkyl ether, particularly 2-ethyl hexyl glycerin ether displays good antimicrobial effect, inhibits enzymes or catalysts which are responsible for the odor formation from the primarily odorless sweat, have an effect on the sweat-gland secretion, whereby sweat secretion is reduced.

In view of above teachings, it would have been obvious to one of ordinary skill in the art to modify the anti-microbial composition disclosed by Modak and Jampani because Beilfuss teaches that composition comprising octoxyglycerin enhances the activity of anti-microbial agents and have good penetration capacity into the skin and/or the ability to penetrate deeper into the upper layers of the epidermis may also possibly be decisive. Further composition comprising octoxyglycerin have excellent stability, compatibility with other active ingredients and auxiliaries support for the dispersing and co-emulsifying action in cosmetic preparations.

One of ordinary skill in the art at the time the invention was made would have been motivated to incorporate octoxyglycerin into anti-microbial composition, because such glycerin monoalkyl ethers in cosmetic preparations would provide a reasonable expectation of success in producing the advantageous properties as stated above and the claimed invention.

Applicant's arguments filed on 09/06/2007 have been fully considered but they are not persuasive.

Applicant assert that Modak or Jampani in view of Beilfuss fails to provide any quantifiable results as to any specific antimicrobial activity in the composition and further

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the examiner uses improper hindsight references by choosing various elements of the art to arrive the claimed invention.

This is not persuasive because, firstly the claims are directed to a composition comprising and any composition comprising the ingredients recited in the claims will inherently meet that composition. And second, the claims are not directed to inhibit the growth of both gram(+) and gram(-) bacteria. Therefore the prior art teaching a composition comprising octoxyglycerin, a quaternary ammonium compound, an antimicrobial agent, an iodine compound, and a zinc compound does not have to necessarily/specifically state inhibiting the growth. And also, Beilfuss discloses concentration of glycerin monoalkyl ethers in the range 0.01 to 20 wt% and preferably 0.5 to 10 wt% relative to the ready-to-use deo-composition. Same compounds/ composition must have the same properties.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a Individual compositions comprising octoxyglycerin, a quaternary ammonium compound, an

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antimicrobial agent, an iodine compound, and a zinc compound to be used for the very same purpose.

Conclusion

1. No claims are allowed at this time.
2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the, shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jagadishwar R Samala
Examiner
Art Unit 1618

Zohreh Fay
Primary Examiner
Art Unit 1618

A handwritten signature in black ink, appearing to read 'Zohreh Fay', is positioned below the printed name and title.